REMARKS

Claims 1, 7, 9, 14, 15, 26, 28–30, 36–38, 40–42, 45–47, 49–51, and 60–66 are pending in this application. Non-elected claim 26 has been withdrawn from consideration by the Examiner. By this Amendment, claims 1, 7, 14, 15, 26, 28–30, 36–38, 45–47, and 49–51 are amended. Support for the amendments to the claims may be found, for example, in the claims and specification as originally filed. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Allowable Subject Matter

Applicants thank the Examiner for the indication that claims 65 and 66 contain allowable subject matter.

II. Rejection under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1, 7, 14, 15, 28–30, 36–38, 45–47, 49–51, and 60–64 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. By this Amendment, the claims are amended in light of the Examiner's comments. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejection under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 1, 7, 9, 14, 15, 28–30, 36–38, 45–47, 49–51, and 60–64 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

In addition to the previous arguments made of record in traverse of this rejection (*see* June 2003 Amendment, March 2004 Amendment After Final Rejection, November 2005 Amendment, and August 2006 Request for Reconsideration), Applicants include the following remarks.

The Office Action asserts:

> There needs to be a structural/functional nexus that allows the skilled artisan to reasonably envisage those molecules that are currently being claimed. The disclosure is deficient in this attempt as set forth in rejection *supra*. Simply providing a nucleotide sequence in the absence of further identification of the molecular determinants modulating the desired properties of said sequence is insufficient to put the entire genus of claimed variance within the possession of the applicants.

See Office Action, paragraph bridging pages 8–9.

Applicant's respectfully disagree with the Office Action's assertion that there "needs to be a structural/functional nexus that allows the skilled artisan to reasonably envisage those molecules that are currently being claimed." A structural/functional nexus is only **one** of the options available to sufficiently show that the applicant was in possession of the claimed genus. MPEP §2163 provides that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that the applicant was in possession of the claimed genus.

At least three non-binding and non-precedential decisions issued by the Board of Patent Appeals and Interferences (BPAI) are indicative that a structural/functional nexus does not need to be established to sufficiently show that an applicant was in possession of the claimed genus.

A. *Ex Parte Bandman*

In *Ex Parte Bandman* (Appeal No. 2004-2319) (copy attached), the Board reversed an Examiner's rejection of polynucleotide claims under 35 U.S.C. §112, first paragraph, as

failing to comply with the written description requirement. Claims 3 and 12 are representative of the subject matter that was on appeal, and read as follows:

> 3. An isolated polynucleotide encoding a polypeptide selected from the group consisting of:
> a) a polypeptide comprising the amino acid sequence of SEQ ID NO: 1; and
> b) a polypeptide comprising a naturally occurring amino acid sequence at least 95% identical to the amino acid sequence of SEQ ID NO: 1.
>
> 12. An isolated polynucleotide selected from the group consisting of:
> a) a polynucleotide comprising the polynucleotide sequence of SEQ ID NO: 2,
> b) a polynucleotide comprising a naturally occurring polynucleotide sequence at least 95% identical to the polynucleotide sequence of SEQ ID NO: 2,
> c) a polynucleotide having a sequence complementary to a polynucleotide of a),
> d) a polynucleotide having a sequence complementary to a polynucleotide of b) and
> e) an RNA equivalent of a)-d).

The Board pointed out that the rejection contended that the specification provided only a single representative species—an isolated polynucleotide consisting of SEQ ID NO: 2, and that the rejection further asserted that "[t]here is no disclosure of any particular structure to function/activity relationship in the single disclosed species." *See Ex Parte Bandman*, page 3. The Board disagreed with these assertions, citing to two Federal Circuit cases. First, the Board, at page 3, stated:

> The written description requirement of 35 U.S.C. § 112, first paragraph, does not require a description of the complete structure of every species within a chemical genus. See *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. § 112, ¶1, contain a written description of a broadly claimed invention without describing all species the claim encompasses.").

Second, the Board discussed *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1602 (Fed. Cir. 2002). On page 4, the Board pointed out:

> In *Enzo-Biochem*, the court refined the approach advanced by *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1998), adopting an example offered in the USPTO guidelines having facts that contrasted with those of *Eli Lilly*, wherein the written description requirement would be met. Adequate written description may be present for a genus of nucleic acids based on their hybridization properties, "if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." *Enzo Biochem*, 296 F.3d at 1327, 63 USPQ2d at 1615.

The Board found that the complete structure of the polynucleotide of SEQ ID NO: 2 had been described, and that the claimed genus was limited to a polynucleotide comprising a naturally occurring polynucleotide sequence at least 95% identical to the polynucleotide sequence of SEQ ID NO: 2. *Id* at page 5. In addition, the Board also found that the complete structure of the polypeptide of SEQ ID NO: 1 had been described, and that the claimed genus was limited to polypeptides comprising a naturally occurring amino acid sequence at least 95% identical to the amino acid sequence of SEQ ID NO: 1. *Id.*

The Board concluded, "While the examiner asserts that the specification provides no disclosure of any particular structure to function/activity relationship in the single disclosed species, the examiner has not adequately explained and/or provided evidence to support that assertion. Thus, the rejection...under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, is reversed." *Id.*

B. *Ex Parte Au-Young*

In *Ex Parte Au-Young* (Appeal No. 2003-1817) (copy attached), the Board reversed an Examiner's rejection of polynucleotide claims under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 45 and 52 are representative of the subject matter that was on appeal, and read as follows:

> 45. An isolated polynucleotide encoding a polypeptide selected from the group consisting of:

a) an amino acid sequence of SEQ ID NO:1 or SEQ ID NO:3, and

b) a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or SEQ ID NO:3, and a polynucleotide complementary thereto.

52. An isolated polynucleotide comprising a sequence selected from the group consisting of:

a) a polynucleotide sequence of SEQ ID NO:2 or SEQ ID NO:4,

b) a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 or SEQ ID NO:4,

c) a polynucleotide sequence complementary to a), and

d) a polynucleotide sequence complementary to b).

The Board, on page 3, quoted from the Examiner's Answer to the Appeal Brief the Examiner's reasons for the rejection:

> Allelic variants are alternate forms of a gene which have at least one mutation in the nucleotide sequence which may result in mRNAs (polypeptides) with altered function. With regard to a naturally-occurring human polynucleotide sequence variant, there is no description in the specification of any mutational site that exist in nature, and there is no description of how the structure of SEQ ID NOs: 2 or 4 relates to the structure of any allele including strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others.

In response to the Examiner's assertions, the Board cited to *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Specifically, the Board pointed out that the *Eli Lily* decision addressed the manner by which a genus of cDNAs might be described when it stated, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *See Ex Parte Au-Young*, page 4 (citation omitted).

The Board found that claims 45 and 52 defined a genus of polynucleotides by way of two significant qualifiers: 1) that the polynucleotide must be "naturally occurring," and 2) that the polynucleotide must be "at least 90% identical" to the recited sequence identifiers. *Id.* The Board concluded, "In our view, these two limitations adequately describe the genus of polynucleotides encompassed by claim 45 b) and 52 b) without these claims further including a functional limitation." *Id* at page 5.

C. *Ex Parte Sun*

In *Ex Parte Sun* (Appeal No. 2003-1993) (copy attached), the Board reversed an Examiner's rejection of polynucleotide claims under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 31 is representative of the subject matter that was on appeal, and reads as follows:

> 31. An isolated wee1 nucleic acid comprising a member selected from the group consisting of:
> (a) a polynucleotide that encodes a polypeptide of SEQ ID NO:2.;
> (b) a wee1 polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1;
> (c) a polynucleotide comprising the coding sequence set forth in SEQ ID NO:1; and
> (d) a polynucleotide complementary to a polynucleotide of (a) through (c).

In support of the rejection, the Examiner made the following arguments:

1. The "specification does not set forth what specific structural or physical features define the claimed isolated nucleic acids and transgenic cells, plants and seeds."
2. One skilled in the art "could not predict the structure and function of isolated nucleic acids comprising a wee1 polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 or a polynucleotide complementary thereto, or cells, plants and seeds transformed therewith."
3. "The physical features of the claimed isolated nucleic acids and transgenic cells, plants, and seeds cannot be ascertained in the absence of information about the functional activities of these nucleic acids."
4. "The specification does not disclose the effect of incorporating the claimed isolated nucleic acids into the genome of a cell or plant."

5. "Applicant's [sic] own specification fails to teach a single representative species with 80% identity and WEE1 function."

See Ex Parte Sun, pages 7–8.

In response to argument (5), the Board noted that they did "not find the fact that the specification does not specifically teach the structure of a species with 80% identity and WEE1 function to be dispositive of the written description issue." *Id* at page 8. The Board went on to state that the specification specifically described the chemical structures of a polynucleotide that encodes a polypeptide of SEQ ID NO:2 and a polypeptide comprising the coding sequence set forth in SEQ ID NO:1, and that the specification provided an example of how to screen for WEE1 activity. The Board found that these disclosures constituted "sufficiently detailed, relevant identifying characteristics of the claimed subject matter consistent with *Enzo*." *Id.*

* * * * *

Without conceding to the propriety of the rejection, claims 1, 7, 14, and 15 are amended to recite "sequences derived from or equivalent to" with respect to the sequences that recite a percent identity to any of SEQ ID NOs:6, 9, or 12, and their complementary sequences. Support for these amendments may be found, for example, in the claims as originally filed (original claim 1 recited, "the sequences equivalent to sequences (i) or (ii), in particular the sequences having, for every series of 100 contiguous monomers, at least 50%, and preferentially at least 70% homology with sequences (i) or (ii) respectively") and in the specification, for example, at paragraphs [0031] to [0034].

Claims 1, 14, and 15 were previously rejected under 35 U.S.C. §112, second paragraph, because it was asserted that the recitation of "sequence equivalent to" was "vague and indefinite since the precise structural characteristics of these sequences are not clearly set forth." *See* December 2002 Office Action, item 4. Although the recitation "sequence

equivalent to" was deleted from the claims in response to the rejection, Applicants submit that the recitation of "sequences derived from or equivalent to" is definite for the following reasons.

A fundamental principle contained in 35 U.S.C. §112, second paragraph, is that applicants are their own lexicographers. Where an explicit definition is provided by the applicants for a term, that definition will control interpretation of the term as it is used in the claim. If one skilled in the art is able to ascertain the meaning of terms recited in a claim in light of the specification, 35 U.S.C. §112, second paragraph, is satisfied. *See* MPEP §2173.02.

The terms "equivalent" and "derived" are explicitly discussed in the specification. For example, paragraph [0031] states:

> Two nucleotide or peptide sequences are said to be equivalent or derived with respect to each other, or with respect to a reference sequence, if functionally the corresponding biopolymers can play substantially the same role, without being identical, in relation to the application or use considered, or in the technique in which they are involved; particularly equivalent are two sequences obtained because of the natural variability, in particular spontaneous mutation, of the species from which they were identified, or induced mutation, as well as two homologous sequences, the homology being defined below.

(Emphasis added). Furthermore, paragraph [0034] states:

> Any nucleotide fragment is said to be equivalent to or derived from a reference fragment if it has a nucleotide sequence equivalent to the sequence of the reference fragment; according to the preceding definition, in particular equivalent to a reference nucleotide fragment are:
>
> (a) any fragment capable of hybridizing, at least partially, with the complementary to the reference fragment,
>
> (b) any fragment whose alignment with the reference fragment leads to the identification of identical contiguous bases, in a greater number than with any other fragment obtained from another taxonomic group,
>
> (c) any fragment resulting or capable of resulting from the natural variability of the species from which it is obtained,

(d) any fragment which may result from genetic engineering techniques applied to the reference fragment,

(e) any fragment, containing at least eight contiguous nucleotides, encoding a peptide homologous or identical to the peptide encoded by the reference fragment,

(f) any fragment different from the reference fragment through insertion, deletion, substitution of at least one monomer, extension, or shortening at least at one of its ends; for example, any fragment corresponding to the reference fragment, flanked at least at one of its ends by a nucleotide sequence not encoding a polypeptide.

(Emphasis added). Applicants submit that one skilled in the art would be able to ascertain the meaning of the terms "equivalent to" and "derived from" recited in the amended claims in light of the specification and, thus, 35 U.S.C. §112, second paragraph, is satisfied.

Furthermore, Applicants respectfully submit that these same disclosures provide "a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" as provided by *Eli Lily* as one method of sufficiently providing written description support for a claimed genus of nucleotide sequences. *See* discussion *supra*. Specifically, items (a) through (f) of paragraph [0034] describe distinguishing identifying characteristics which permit a person skilled in the art to recognize that the applicant had possession of the claimed invention.

Reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejection Under 35 U.S.C. §102

The Office Action rejects claims 1, 7, 14, 15, and 60 under 35 U.S.C. §102(b) as being anticipated by Boehringer Mannheim et al. (1994). Applicants respectfully traverse the rejection.

By this Amendment, claims 1, 7, 14, and 15 are amended to recite "full-length sequence set forth in" as suggested by the Examiner. Claim 60 depends from claim 1. In light of the amendments, the rejection of claims 1, 7, 14, 15, and 60 over Boehringer

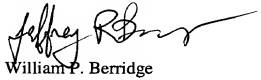
Mannheim et al. is moot. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachments:

Ex Parte Bandman (Appeal No. 2004-2319)
Ex Parte Au-Young (Appeal No. 2003-1817)
Ex Parte Sun (Appeal No. 2003-1993)

Date: August 7, 2007

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